JFW/1621

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Akira NISHIYAMA, et al.

Docket No: Q95734

Appln. No.: 10/586,337

Group Art Unit: to be assigned

Confirmation No.: to be assigned

Examiner: to be assigned

Filed: July 14, 2006

For: PROCESSES FOR PRODUCING OPTICALLY ACTIVE 1-SUBSTITUTED 2-METHYLPYRROLIDINE AND INTERMEDIATE THEREFOR

LETTER

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Information Disclosure Statement filed July 14, 2006, for the convenience of the Examiner, Applicant is now able to provide, and attaches hereto, a copy of an English translation of the International Preliminary Report on Patentability (IPRP).

No additional cited art documents are submitted or listed herewith, since the documents cited in the IPRP were previously cited and listed in the Information Disclosure Statement filed July 14, 2006.

Respectfully submitted,

Sheldon I. Landsman/by Joseph Ruff

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WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: October 6, 2006

PATENT COOPERATION TREATY

PCT/JP2005/000575

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44*bis*.3(c) and 72.2)

To:

KANEKA CORPORATION
2-4, Nakanoshima 3-chome
Kita-ku, Osaka-shi
Osaka 5308288
JAPON

Date of mailing *(day/month/year)* 31 August 2006 (31.08.2006)	
Applicant's or agent's file reference B040007WO01-	**IMPORTANT NOTIFICATION**
International application No. PCT/JP2005/000575	International filing date *(day/month/year)* 19 January 2005 (19.01.2005)
Applicant KANEKA CORPORATION et al	

1. **Transmittal of the translation to the applicant.**

☑ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. **Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Masashi Honda
Facsimile No. +41 22 338 82 70	Facsimile No. +41 22 338 82 70

受付 05.9.11 意外知財

Form PCT/IB/338 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference B040007WO01-	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/JP2005/000575	International filing date *(day/month/year)* 19 January 2005 (19.01.2005)	Priority date *(day/month/year)* 30 January 2004 (30.01.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KANEKA CORPORATION		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 22 August 2006 (22.08.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Masashi Honda e-mail: pt08@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference B040007WO01-	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/000575	19.01.2005	30.01.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant
KANEKA CORPORATION

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP Facsimile No.	Authorized officer Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/000575

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/000575

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2-10	YES
	Claims	1, 11-12	NO
Inventive step (IS)	Claims	2-9	YES
	Claims	1, 10-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP, 49-55629, A (Esso Research and Engineering Co.), 30 May, 1974 (30.05.74)

Document 2: "Asymmetric Synthesis via Lithium Chelates," (Thomas Whitney et al.), Advances in Chemistry Series, 1974, Vol. 130, pages 270-280

Document 3: "Asymmetric Synthesis via Lithium Chelates," (Thomas Whitney et al.), Polymer Preprints, 1972, Vol. 13, No. 2, pages 688-692

Document 4: "Preparation of γ-acetopropyl alcohol from γ-butyrolactone.," (A. B. Letunova et al.), Khimiko-Farmatsevticheskii Zhurnal, 1977, Vol. 11, No. 12, pages 121-123

Document 5: "The efficient resolution of protected diols and hydroxyl aldehydes by lipases: steric auxiliary approach and synthetic applications," (Kim et al.), Bioorganic and Medicinal Chemistry Letters, 1996, Vol. 6, No. 1, pages 71-76

Document 6: "Purification and properties of an NADPH-dependent carbonyl reductase from the human brain. Relationship to prostaglandin 9-ketoreductase and xenobiotic ketone reductase," (B. Wermuth), The Journal of Biological Chemistry, 1981, Vol. 256, No. 3, pages 1206-1213

Document 7: "A novel NADPH-dependent carbonyl reductase with an extremely broad sustrate range from Candida parapsilosis: Purification and characterization.," (Peters Jörg et al.) Enzyme and Microbial Technology., 1993, Vol. 15, pages 950-958

Claim 1

The subject matter of claim 1 does not appear to be novel, since it is described in documents 1-3 cited in the ISR.

Documents 1-3 describe that 5-hydroxy-2-pentanone is asymmetrically reduced to an optically active 1, 4-pentanediol by using a lithium chelate compound (document 1: page 14, table 1, document 2: pages 276-277, Table 1, document 3: page 689, Table).

Therefore, the inventions described in documents 1-3 cannot be distinguished from the subject matter of claim 1.

Claim 10

The subject matter of claim 10 does not appear to involve an inventive step in view of documents 1-3 and document 4 cited in the ISR.

Document 4 describes that 5-hydroxy-pentanone can be acquired from 2-acetyl-γ-butyrolactone (document 4: page 121). It is obvious for an expert in the relevant technical field to

produce 5-hydroxy-pentanone by acid-hydrolyzing 2-acetyl-γ-butyrolactone. Besides, a person skilled in the art could have easily employed 5-hydroxy-pentanone produced as a material for producing the optically active 1, 4-pentanediol described in documents 1-3.

Claims 11-12

The subject matters of claims 11-12 do not appear to be novel, since they are described in document 5 cited in the ISR.

Document 5 describes that an optically active 1-benzyl-2-methylpyrrolidine can be acquired by making 1, 4-pentanediol be mesyl (methane sulfonic acid ether) and furthermore by making it react with benzylamine (document 5: page 75, Scheme 4).

Therefore, the invention described in document 5 cannot be distinguished from the subject matters of claims 11-12.

Claims 2-9

The subject matters of claims 2-9 appear to be novel and to involve an inventive step in view of documents 1-5 and documents 6-7cited in the ISR.

The constitution, in which a proenzyme is used for reducing 5-hydroxy-2-pentanone asymmetrically, is not described in any of documents 1-7. Moreover, it is not obvious for a person skilled in the art either that an efficient process for producing an optically active 1, 4-pentanediol can be presented by using the proenzyme above-mentioned.